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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,511	12/11/2003	Jennifer Zhao	P-11597.00	9218
27581	7590	08/01/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,511

Applicant(s)

ZHAO ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 1 and 18, the phrase "the first bore being of a first bore diameter...less than the first connector block bore diameter extending along a portion of the first bore" is vague because it is unclear whether "the first bore" is the same as the "first connector block bore", "lead connector element bore", or "first connector bore". In other words, it seems as if the language is claiming "a first bore having a first bore diameter...less than the first bore diameter along a portion of the first bore". Examiner has interpreted the claim to recite a bore having two diameters, one being smaller than the other and threaded, but the syntax of claims 1 and 18 should be amended for clarity.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 5, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko (US 4,316,471 hereinafter "Shipko") in view of Acken (US 5,509,928, hereinafter "Acken"). Shipko discloses the essential features of the claimed invention including the following:

6. In regards to claim 1, 7, 8, and 10, Shipko discloses an implantable device (19) having a header (41) and couples a lead via a tool (87). The connector header has a header bore (unlabelled cavity of 55), a header grommet aperture with a sidewall (41 at 57), and a connector block (45) with a threaded bore (unlabelled cavity of 45) aligned with the grommet aperture (Fig. 3) adapted to receive a medical lead (51). The grommet (65) is formed of an elastomer (col. 1, line 67). Shipko further discloses that the setscrew body (71) has a socket (83) and is disposed between the grommet (65) and connector block (45) (See Fig. 3, portion of setscrew between 65 and 45), the setscrew has a thread mating with the connector block (Fig. 3), the socket head (75) has a head diameter exceeding the bore diameter (Fig. 3), and the socket head is

engaged by a tool inserted through the grommet (Fig. 3, 65) to tighten or loosen the setscrew and the head diameter prevents advancement of the setscrew through the bore (Fig. 3). Additionally, Shipko's device has a first threaded bore (47) having a smaller diameter than a second bore (unlabelled bore receiving elastomer element 65), and the socket head is fully recessed within the first connector block bore (Fig. 3) and displaced from the grommet (65). Although Shipko discloses that the grommet seals against another element (i.e. the setscrew), Shipko does not disclose that the grommet is self-sealing. Acken teaches of a grommet with a self-sealing passage between the inner and outer grommet walls (Figs. 4 and 5) to provide an additional level of fluid sealing from the electrical contacts. Therefore, it would have been obvious to modify Shipko's invention by providing a self-sealing passage between the inner and outer grommet walls to provide an additional level of fluid sealing from the electrical contacts.

7. In regards to claims 2 and 18, the setscrew is rotatable by a setscrew tool inserted through the grommet (as in Fig. 3) until the setscrew is retracted into frictional engagement with the grommet (65), which stabilizes the setscrew (as in Fig. 4).

8. In regards to claims 3 and 17, the header has a retention space (unlabelled voids in Fig. 4) for receiving the setscrew body when in the retracted position.

9. In regards to claims 5 and 15, the socket head comprises a plastic (col. 4, line 4) ring (81) molded around a portion of the setscrew body (73).

10. Claims 4, 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken. Shipko discloses the essential elements of the claimed invention except for a setscrew head that is formed with a funnel-shaped

opening without a sharp cutting edge. Acken teaches of a setscrew head that is "formed with" (i.e. all components are formed together) a funnel shaped opening (80) that guides a tool (inherent) and provides space accommodating displaced elastomer material (col. 4, line 65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Shipko's invention with a setscrew head that is "formed with" a funnel shaped opening that guides a tool and provides space accommodating displaced elastomer material.

11. Alternatively, claims 4, 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken, as applied to claims 1 and 2 above, and further in view of Jackson (US 6,056,753 hereinafter "Jackson"). Shipko's modified invention discloses the essential elements of the claimed invention except for a setscrew head that is formed with a funnel-shaped opening without a sharp cutting edge. Jackson teaches of a setscrew with a funnel-shaped opening without a sharp cutting edge (col. 7, line 5) to facilitate insertion of a tool. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Shipko's modified invention with a funnel-shaped opening without a sharp cutting edge to facilitate insertion of a tool.

12. Claims 6, 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken, as applied to claims 1 and 2 above, and further in view of Fischer (US 791,548 hereinafter "Fischer"). Shipko's modified invention discloses the essential features of the claimed invention except for a socket that extends for substantially the full length of the setscrew body. Fischer teaches of a setscrew with a

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socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew (line 31). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shipko's modified invention by providing a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken (or Shipko in view of Acken and Jackson), as applied to claim 12 above, and further in view of Fischer. The modified invention of Shipko discloses the essential features of the claimed invention except for a socket that extends for substantially the full length of the setscrew body. Fischer teaches of a setscrew with a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew (line 31). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shipko's invention by providing a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-9, 12, and 15-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-31 of copending Application No. 10/732,947. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application's claims are more narrow and meet the limitations of the broader claims of this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

16. Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. In regards to the argument that Shipko's element 65 is not a penetrable grommet, Examiner maintains the position that, because a tool is inserted through the aperture, the element

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is penetrable and is a flexible loop that supports, thus meeting the limitation of "penetrable grommet".

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

MR JK
7/25/06

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GEORGE R. EVANISKO
PRIMARY EXAMINER

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